REMARKS

Claims 3 and 5-8 have been amended. Claims 1-8 are pending in the instant application. No new matter has been added as a result of the above-described amendments. The rejections set forth in the Office Action have been overcome by amendment or are traversed by argument below.

1. Election/Restriction

The Office Action states that newly amended claims 3-8 are directed, in part, to inventions that are independent or distinct from the invention originally claimed because claim 3 encompasses the non-elected invention of Group 1, as identified in the Restriction Requirement mailed April 11, 2001, as well as a multitude of other distinct inventions comprising nucleotide sequences encoding polypeptides having amino acid sequences that differ from the amino acid sequence of the polypeptide encoded by the elected invention. Claim 3 has been amended to remove non-conservative substitutions. The Action alleged that substitution involving asparagine and threonine is not conservative. However, both asparagine and threonine have polar, uncharged side chains. The conservative substitutions shown in the specification are merely exemplary, not exclusive. Thus, one of skill in the art would recognize that a substitution involving asparagine and threonine is conservative. Since claim 3 does not encompass a broader scope than original claim 3, Applicants respectfully request that the full scope of the subject matter recited in claim 3 be considered.

2. Specification

The specification was objected to because American Type Culture Collection™ was not properly identified as a trademark at page 2, line 1. The specification has been amended to properly identify the mark thereby obviating this objection.

3. Objection to claims 3-8

The Office Action asserts an objection to claims 3-8 because claim 3 is drawn in the alternative to the subject matter of non-elected inventions.

As described in section 1 above, Applicants have amended claim 3 so that it is no longer

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drawn in the alternative to the subject matter of non-elected inventions. Applicants, therefore, respectfully request that this objection be withdrawn.

4. Rejections of claims 5 and 6 under 35 U.S.C. § 101

Claims 5 and 6 stand rejected under 35 U.S.C. §101 as directed to non-statutory subject matter. The claims have been amended to recite "isolated host cell" rather than "host cell" thereby obviating this rejection.

5. Rejections of claims 5 and 6 under 35 U.S.C. § 112, first paragraph

Claims 5 and 6 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly not enabled for host cells that are not isolated. As discussed above, the claims have been amended to recite "isolated host cell" rather than "host cell." Applicants submit that the amendment to the claims renders moot the rejection under 35 U.S.C. §112, first paragraph. Consequently, Applicants respectfully request that this ground of rejection be withdrawn.

6. Rejections of claims 1-5 and 7 under 35 U.S.C. § 102

Claims 1-5 and 7 stand rejected under 35 U.S.C. § 102(b), as being anticipated by Hillier *et al.* (GenBank® EST database Accession No. AA422178). The Action states that while Hillier *et al.* does not disclose a nucleotide sequence as set forth in SEQ ID NO: 4 or encoding a polypeptide as set forth in SEQ ID NO: 5, Hillier *et al.* does disclose a nucleotide sequence encoding a polypeptide that is 100% identical to that amino acid sequence set forth in SEQ ID NO: 5 over the region spanning from amino acid residues 1 to 76. The Action asserts that the nucleic acid molecule of Hillier *et al.* comprises a polynucleotide sequence (between residues 1 to 60) that is complementary to SEQ ID NO: 4. Thus, the Action alleges that Hillier *et al.* anticipates the invention of claim 1. Applicants respectfully traverse.

Hillier *et al.* does not disclose or suggest a nucleotide sequence that is complementary to the sequence of, for example, SEQ ID NO: 4. However, even if Hillier *et al.* were assumed to disclose

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or suggest such molecules, the sequences cannot anticipate claim 1, because the claim does not encompass nucleic acid molecules comprising a nucleic acid sequence that is complementary to a *portion* of SEQ ID NO: 4. Consequently, Applicants respectfully submit that the nucleic acid molecule of Hillier *et al.* does not anticipate claim 1. Applicants, therefore, request that this ground of rejection be withdrawn.

The Action also asserts that Hillier *et al.* is "deemed the same as the claimed nucleic acid molecule comprising the nucleotide sequence of the DNA insert in the ATCC Deposit No. PTA-1755, which necessarily encodes a variant of the polypeptide encoded by SEQ ID NO: 4." The Action supports this assertion by alleging that the specification teaches at page 2, lines 26-29 that the DNA insert comprises the polynucleotide sequence of an allelic variant or splice variant of the nucleotide sequence of SEQ ID NO: 4. Page 2, however, does not teach that the nucleotide insert of ATCC Deposit No. PTA-1755 is a variant of the polypeptide encoded by SEQ ID NO: 4. The specification indicates on page 84, lines 15-19 that the ATCC Deposit No. PTA-1755 comprises a cDNA encoding a human Secs-1 polypeptide and *not* an allelic variant or splice variant of the nucleotide sequence of SEQ ID NO: 4. Secs-1 cDNA and polypeptide are described in Example 1 and shown in Figure 2. Thus, the cDNA in ATCC Deposit No. PTA-1755 is not a variant as alleged by the Action. Therefore, the Hillier nucleic acid molecule cannot anticipate the claims.

The Action next asserts that since the nucleotide sequence of Hillier *et al.* comprises, for example, the region of the nucleotide sequence of SEQ ID NO: 4 spanning nucleotide residues 29 to 130, which encodes amino acid residues 1-34 of SEQ ID NO: 5, the nucleotide sequence of Hillier *et al.* comprises a region of the nucleotide sequence of SEQ ID NO: 4, or the DNA insert in ATCC Deposit No. PTA-1755, encoding a polypeptide fragment of at least about 25 amino acid residues, but not more than 80 amino acid residues, wherein upon injection into an animal the polypeptide fragment produces an antibody that binds to the polypeptide as set forth in SEQ ID NO: 5. Applicants traverse this rejection.

Applicants respectfully disagree with the Action's assertion that since the nucleotide sequence of Hillier *et al.* comprises, for example, the region of the nucleotide sequence of SEQ ID NO: 4 spanning nucleotide residues 29 to 130, which encodes amino acid residues 1-34 of SEQ ID NO: 5, the nucleotide sequence of Hillier *et al.* comprises a region of the nucleotide sequence of

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SEQ ID NO: 4, or the DNA insert in ATCC Deposit No. PTA-1755, encoding a polypeptide fragment of at least about 25 amino acid residues, but not more than 80 amino acid residues, wherein upon injection into an animal the polypeptide fragment produces an antibody that binds to the polypeptide as set forth in SEQ ID NO: 5. Applicants note first that claim 2 recites a region of the nucleotide sequence of SEQ ID NO: 4, or the DNA insert in ATCC Deposit No. PTA-1755, encoding a polypeptide fragment of at least about 25 amino acid residues, but not more than 80 amino acid residues. Applicants also note that the specification positively recites that fragments of the disclosed sequences (*i.e.*, Secs-1 polypeptide fragments) are encompassed within the scope of the invention (page 9, line 14 to page 10, line 2). Hillier *et al.*, on the other hand, does *not* recite fragments of the polypeptide encoded by the nucleotide sequence disclosed in GenBank® EST database Accession No. AA422178. In fact, as described in Applicants' response to the Office Action mailed August 9, 2001, Hillier *et al.* does not even teach a full-length polypeptide, let alone polypeptide fragments of that full-length polypeptide. What Hillier *et al.* does disclose is a nucleotide sequence that one of ordinary skill in the art would deduce encodes a polypeptide of 98 amino acids. Applicants contend that because no single member of the genus of nucleic acid molecules defined by claim 2 encodes a polypeptide of greater than 80 amino acids, the nucleotide sequence disclosed by Hillier *et al.* encodes a polypeptide of 98 amino acids, and Hillier *et al.* does not disclose fragments of the nucleotide sequence of GenBank® EST database Accession No. AA422178, Hillier *et al.* cannot anticipate claim 2.

Because Hillier *et al.* does not disclose a nucleotide sequence that meets each and every limitation of the claimed invention, GenBank® EST database Accession No. AA422178 cannot anticipate claims 1-5 and 7, as amended. Applicants, therefore, respectfully request that this ground of rejection be withdrawn.

Claims 1-5 and 7 also stand rejected under 35 U.S.C. § 102(b), as being anticipated by GenBank® Accession No. AA283751. Specifically, the Action asserts that the polynucleotide sequence of the insert in the clone available from IMAGE Consortium is an inherent property, and thus, while the published sequence differed from SEQ ID NO: 4, the sequence of the insert in the clone anticipates SEQ ID NO: 4. Applicants traverse this rejection.

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As discussed in Applicants' Response dated November 20, 2003, the *actual sequence* of the insert in the above-mentioned clone was not publicly accessible. As pointed out in *In re Hall*:

> Because there are many ways in which a reference may be disseminated to the interested public, "public accessibility" has been called the touchstone in determining whether a reference constitutes a "printed publication" bar under 35 U.S.C. § 102(b). ... The proponent of the publication bar must show that prior to the critical date the reference was sufficiently accessible, at least to the public interested in the art, so that such a one by examining the reference could make the claimed invention without further research or experimentation. *In re Hall*, 781 F.2d 897, 898-99 (Fed. Cir. 1986) (citations omitted).

Furthermore, because GenBank™ Accession No. AA283751 teaches away from the sequence disclosed by the Applicants, one of ordinary skill in the art would expect that the clone available from the IMAGE Consortium would comprise a sequence substantially different from the sequence disclosed by the Applicants. The present situation differs from the situation of *In re Hall*. Specifically, the reference of *In re Hall* was a thesis that was *properly catalogued* in a German university library. In contrast, the clone deposited by the IMAGE Consortium was *improperly catalogued* because GenBank™ Accession No. AA283751 was published with the incorrect sequence. Consequently, Applicants maintain the position that the clone (IMAGE:713624) does not constitute a proper anticipatory reference under 35 U.S.C. §102(b) because the actual sequence of the DNA insert was not "sufficiently accessible" to those of skill in the art. The skilled artisan would have relied on the published sequence, which taught away from the sequence of SEQ ID NO: 4. Thus, Applicants respectfully request that the Examiner withdraw this ground of rejection.

7. Rejections of claims 1-8 under 35 U.S.C. § 103

The Office Action asserts a rejection of claims 1-8 under 35 U.S.C. § 103(a), as being unpatentable over either Hillier *et al.* (GenBank® EST database Accession No. AA422178) or Database GENBANK Accession No AA283751, in view of Bendig, 1988, *Genet. Eng.* 7:91-127 and

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Niwa *et al.*, 1991, *Gene* 108:193-99.

Applicants submit that the arguments set forth above traversing the corresponding rejections under 35 U.S.C. §102 successfully overcome the alleged rejections under 35 U.S.C. §103. Consequently, Applicants respectfully request that the rejection be withdrawn.

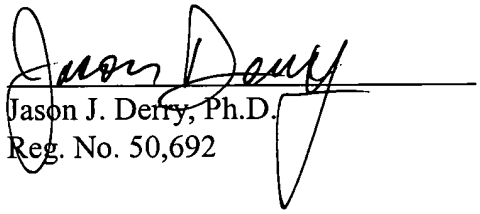
CONCLUSIONS

Applicants respectfully contend that all conditions of patentability are met in the pending claims as amended. Allowance of the claims is thereby respectfully solicited.

If Examiner Rawlings believes it to be helpful, he is invited to contact the undersigned representative by telephone at 312-913-0001.

Respectfully submitted,
McDonnell Boehnen Hulbert & Berghoff LLP

Dated: September 27, 2004

By: 
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